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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/930,494	08/16/2001	Reid W. Von Borstel	1331-352	1560
23117	7590	04/12/2006	EXAMINER	
NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			LEWIS, PATRICK T	
			ART UNIT	PAPER NUMBER

1623

DATE MAILED: 04/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/930,494

Applicant(s)

VON BORSTEL ET AL.

Examiner

Patrick T. Lewis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15, 18-41 and 47-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15, 18-41 and 47-49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                                             |                                                                                         |
|---------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                                            | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                                        | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>01262006</u> | 6) <input type="checkbox"/> Other: _____                                                |

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election without traverse of Group I in the reply filed on July 21, 2003 is acknowledged.

***Applicant's Response Dated January 26, 2006***

2. Claims 1-15, 18-41 and 47-49 are pending. An action on the merits of claims 1-15, 18-41 and 47-49 is contained herein below.
3. The provisional rejection of claims 1-15, 21, 23, 27, 31-32, 37-41, and 47 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 48-59 of copending Application No. 09/763,955 is maintained for the reasons of record as set forth in the Office Action dated July 26, 2005.
4. The rejection of claims 1-15, 18-32, and 47-49 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record as set forth in the Office Action dated July 26, 2005.
5. The rejection of claims 33-36 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record as set forth in the Office Action dated July 26, 2005.
6. The rejection of claims 1-15, 18-32, and 37-41 under 35 U.S.C. 103(a) as being unpatentable over Page et al. Proc. Natl. Acad. Sci. USA, 1997, Vol. 94, pages 11601-11606 (Page) in combination with von Borstel et al. US 6,316,426 (von Borstel) is

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maintained for the reasons of record as set forth in the Office Action dated July 26, 2005.

***Rejections of Record Set Forth in the Office Action Dated July 26, 2005***

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 1-15, 21, 23, 27, 31-32, 37-41, and 47 are provisionally rejected under obviousness-type double patenting as being the judicially created doctrine of unpatentable over claims 48-59 of copending Application No. 09/763,955. Although the claims are not identical, they are not patentably distinct from each other.

Applicant has not set forth arguments traversing the instant rejection.

9. Claims 1-15, 18-32, and 47-49 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of congenital mitochondrial disease, Alzheimer's Disease, Huntington's Disease, neuromuscular degenerative disease, and pathophysiological consequences of mitochondrial respiratory chain dysfunction, does not reasonably provide enablement for the prevention of congenital mitochondrial disease, Alzheimer's Disease, Huntington's Disease, neuromuscular degenerative disease, and pathophysiological consequences of mitochondrial respiratory chain dysfunction. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

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Claims 33-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant's arguments filed January 26, 2006, have been fully considered but they are not persuasive. Applicant argues that the idea of prevention does not relate to preventing or reversing genetic defects but, rather, compensating for them to prevent full clinical manifestation of their disorder. Applicant has further cited references to support applicant's arguments.

Applicant's arguments relating to the Saydoff et al., Gines et al. and any other publication published after the effective filing date of the instant application have been noted but are not sufficient to overcome the instant rejection. Whether the specification would have been enabling as of the filing date involves consideration of the nature of the invention, the state of the prior art, and the level of skill in the art. The state of the art existing at the filing date of the application is used to determine whether a particular disclosure is enabling as of the filing date. Publications dated after the filing date providing information publicly first disclosed after the filing date generally cannot be used to show what was known at the time of filing. In general, if an applicant seeks to use a publication to prove the state of the art for the purpose of the enablement requirement, the publication must have been published (made available to the public) earlier than the effective filing date of the application.

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Applicant's assertion that the understanding of one of ordinary skill in the art would not have changed significantly over the period of time from 1998 to 2003 has also been noted, however during patent examination, the pending claims must be given their broadest reasonable interpretation consistent with the specification. This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. In the instant case, the specification does not provide a definition of "prevention". In the absence of an express intent to impart a novel meaning to the claim terms, the words are presumed to take on the ordinary and customary meanings attributed to them by those of ordinary skill in the art. Furthermore the claims are rejected under 35 U.S.C. 112, first paragraph, because the disclosure is not enabled for the prevention of congenital mitochondrial disease, Alzheimer's Disease, Huntington's Disease, neuromuscular degenerative disease, and pathophysiological consequences of mitochondrial respiratory chain dysfunction not because the term "prevention" is indefinite. Applicant's description of the instantly employed compositions as being "neuroprotective" or "cytoprotective" has also been noted; however, said terms are not recited in the instant claims.

As set forth in the previous Office Action dated July 26, 2005, there is a tremendous amount of unpredictability and uncertainty in the art. Bren "Alzheimer's: Searching for a Cure", FDA Consumer Magazine, July-August 2003 Issue, Pub No. FDA 04-1318C rev. (Bren) teaches, "'We are still searching for the sequence of events where we can intervene and cure the disease without causing harm'...The two biggest risk factors for getting AD are age and genetics, neither of which is in our control." Bren

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also teaches that therapeutic approaches that are successful in transgenic mice have not been shown to be successful in humans with some actually being harmful. Hollander et al. Am J. Psychiatry (1999), Vol. 156:2, pages 317-320 (Hollander) teaches, "The etiology, pathophysiology, and genetic transmission of autism are not known, but autism may be best understood as a heterogeneous disorder resulting from multiple genetic and environmental factors, often complicated by neurologic, cytogenetic, neurotransmitter, and immunologic abnormalities." The prior art clearly teaches that conditions embraced by the instant claims are not preventable. In the 2003 article, Bren discloses, "No cure or prevention for Alzheimer's disease exists yet...". Cattaneo et al. US 2005/0123922 A1 (Cattaneo) discloses, "At the moment there are no specific therapies available which can prevent symptoms or cure patients affected with Huntington's Disease." See paragraph 0012. Not only does the art teach that many of the conditions are not preventable, the causes are not even known. Indeed, the specification does not provide sufficient support for applicant's claim that Alzheimer's Disease, Huntington's Disease, neuromuscular degenerative diseases, or pathophysiological consequences of mitochondrial respiratory chain dysfunction is prevented by the instant method.

10. Claims 1-15, 18-32, and 37-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Page et al. Proc. Natl. Acad. Sci. USA, 1997, Vol. 94, pages 11601-11606 (Page) in combination with von Borstel et al. US 6,316,426 B1 (von Borstel).

Applicant's arguments filed January 26, 2006 have been fully considered but they are not persuasive. Applicant argues that overlapping symptoms are insufficient to

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establish a prima facie case of obviousness, because it is well recognized that unrelated diseases can have overlapping symptoms.

Applicant's argument that it is not true that all of the conditions recited in the previous Office Action are "necessarily" pathophysiological consequences of mitochondrial respiratory chain dysfunction has been noted; however, the instant methods are drawn to the prevention or treatment of the "consequences" of mitochondrial respiratory chain dysfunction. All of the conditions cited in the prior Office Action are a "consequence" of mitochondrial respiratory chain dysfunction. Therefore, the rejection is still deemed proper. Applicant's argument that unrelated disease can have overlapping symptoms and that although symptoms may look similar, the treatment will vary according to the underlying problem has also been noted; however, it is not necessary that the prior art recognize a previously unappreciated property of a prior art composition or a scientific explanation for the prior art's functioning.

In construing process claims and references, it is the identity of manipulative operations which leads to finding of obviousness. In the instant case, it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. Page teaches the treatment of patients described with a syndrome that included developmental delay, seizures, ataxia, recurrent infections, severe language deficit, and an unusual behavioral phenotype characterized by hyperactivity, short attention span, and poor social interaction with uridine. Developmental delay, seizures, ataxia, recurrent infections, severe language deficit, and an unusual behavioral phenotype characterized by hyperactivity, short



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attention span, and poor social interaction are "pathophysiological consequences of mitochondrial respiratory chain dysfunction". The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant.

### ***Conclusion***


11. Claims 1-15, 18-41 and 47-49 are pending. Claims 1-15, 18-41 and 47-49 are rejected. No claims are allowed.

**Contacts**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 571-272-0655. The examiner can normally be reached on Monday - Friday 10 am to 3 pm (Maxi Flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Dr. Patrick T. Lewis  
Examiner  
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